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MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER

CHEU, CHANGHWA J

| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,475

Applicant(s)

LYNGBERG ET AL.

Examiner

Jacob Cheu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24,48 and 100-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24,48 and 100-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/13/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 6/15/2005 has been received and entered into record and considered.

1. Finality of Office Action

With respect to the previous Final Office Action (mailed on 3/11/2005), examiner would like to withdraw finality due to the presence of new art and new rejections. However, this present Office Action is made final based on the same art and rejections set forth in the previous Office Action (See below).

2. Currently, Claims 1-24, 48, 100-110 are under examination.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-13, 15-24, 48, 100-104, 106-108, 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiagarajan et al. (Euro. Federation Biotech. 1995, page 304) in view of Foster et al. (US 4444879).

Thiagarajan et al. teach immobilizing metabolically viable bacteria on a composite biostructure, i.e. biofilm, for measuring oxygen consumption. (See Introduction)

Thiagarajan et al. teach mixing E. Coli with porous latex polymers and to form a biofilm bacteria/latex biostructure (See page 306, last paragraph). The biofilm can be activated upon hydration (See page 305, first-forth paragraph). However, Thiagarajan et al. do not explicitly teach that the device contains at least a portion of a nonporous latex-derived material.

Foster et al. teach a widely use polymeric resins, i.e. nonporous carboxylated styrene-butadien latex polymers, as the immobilizing substrates in the form of test tube, microtiter plates, "dipsticks", or similar configuration to increase the adsorption of the biological materials on the substrate (Col. 2, line 20-40; See Example 1). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Thiagarajan et al. with the nonporous styrene latex as taught by Foster et al. as substrates to coat upon the biostructure to increase adsorption of the bacteria on the growth plate for more efficient detection.

With respect to the feature of "wherein the biostructure is *obtainable* by process of gravure coating, piezo-electric printing or acoustic printing", the device of Thiagarajan et al. is inherently obtainable by the recited process. The case law has established that the production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art-"[Where] the claimed and prior art products are identical or substantially identical in *structure or composition*, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195

USPQ 430, 433 (CCPA 1977)(emphasis added). This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art. See In re Kind, 207 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143, 144-145 (CCPA 1938); In re Bergy, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

With respect to claims 4-5, the biostructure taught by Thiaragian et al. contains less than 75% by volume of biological materials (See Materials and Methods).

With respect to claims 6-8 and 13, Thiaragian et al. teach using prokaryotes, such as E Coli bacteria to measure the oxygen, e.g. an analyte, consumption (See Abstract).

With respect to claim 9, the biostructure taught by Thiagarajan et al. is desiccation tolerant since the process involving dryness. (page 308, first paragraph)

With respect to claim 11-12 and 22, the bioreactor of Villaverde et al. contains detector, electrodes (See Figure 1).

With respect to claim 16-17, Thiagaragan et al. teach using porous latex of immobilizing bacteria (See Materials and Method).

With respect to claims 18-21, Thiagarajan et al. teach using the TFPR plate as the substrates for growing E Coli. (See Materials and Method).

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With respect to claim 22 and 108, the biostructure taught by Thiagarajan et al. include wires and electrodes for detection and recording signals (See Figures 6-8).

With respect to claim 23-24, Thiagarajan et al. teach that the thickness of the cell layer is approximately 70 microns which is less than 500 microns within the range of the instant invention (See page 306, first paragraph).

With respect to claim 48, 100, 102-104, 106-107, the device of Thiagarajan et al. is a bioreactor for detection of the oxygen consumption, growth rate or gene expression from the E Coli (See page 304, last paragraph). The response by the E Coli can be recorded by electronic signals (See Figure 6-8).

4. Claims 14 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiagarajan et al. in view of Foster et al., and further in view of Cantwell et al. (EP 0288203).

Both Thiagarajan et al. and Foster et al. references have been discussed but are silent in teaching use of a cross-lined latex polymer. Cantwell et al. teach a composite biostructure comprising imbedding cells on the latex polymers (See Abstract). Cantwell et al. teach using different forces for better immobilizing cells on the latex polymers, including cross-linkage method for enhancement of immobilization (See page 2, line 25-30). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Thiagarajan and Foster et al. with the cross-linked latex as taught by Cantwell et al. to increase the immobilizing efficiency in the biostructure.

5. Claim 109 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thiagarajan et al. in view of Foster et al., and further in view of Martens et al. (Analytica Chimica Acta 1994 Vol. 292: 49-63).

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Both Thiagarajan et al. and Foster et al. references have been discussed but are silent in teaching use a porous sealant layer to protect the biostructure.

Martens et al. teach use of a dialysis membrane, e.g. porous sealant layer, to cover the biostructure biofilm for subsequent analysis (See page 53, right column, first paragraph). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Thiagarajan and Foster et al. with the porous sealant layer as taught by Martens et al. to protect the biostructure for subsequent analysis since it merely involves routine skill in the art.

Response to Applicant's Arguments

Foster et al. Patent (US 4444879)

6. Applicant argues that (1) there is no teaching or suggestion that the polymeric resin of Foster et al. could be combined with the device of Thiagarajan et al. to obtain applicant's invention. Particularly, applicant argues that Foster's reference teaches away from applicant's invention because the immunoreactants taught by Foster were covalently bonded to a polymer, thus such a feature would no longer be metabolic active or capable of becoming metabolically active upon hydration. In addition, applicant argues that (2) neither Thiagarajan et al. nor Foster et al. teach or suggest a method to determine the presence of an analyte, or a method wherein a biological material produces a response and emits a signal upon contact with an analyte. Furthermore, applicant argues that (3) the instant method using a printing method selected from gravure coating, piezo-electric printing, or acoustic printing, which is not taught or suggested by either Thiagarajan or Foster et al. Applicant also argues that certain embodiment, e.g. claim 110, includes a three-dimensional biostructure capable of building into a large number of 3 microwells and microtiter plate which is not recognized prior to applicant's invention.

Applicant's arguments have been considered but are not persuasive.

First of all, examiner would like point out that Foster et al. reference providing the material, e.g. nonporous latex-derived polymeric resin, does NOT teach away from the present invention. Applicant's recited this feature of "nonporous latex-derived materials" is merely for the support of the biostructure, such as channel or well (See claim 3). There is nothing novel with respect to the biostructure since Thiagarajan et al. reference has fully anticipated the features of biological materials integrally embedded within the structure (See discussion above). With respect to the nonporous latex material, examiner has indicated that choosing such materials is well-known and widely practiced in the art- "immobilizing substrates in the form of test tube, microtiter plates, "dipsticks", or similar configuration to increase the adsorption of the biological materials on the substrate (Col. 2, line 20-40; See Example 1)(emphasis added). The motivation is for increase absorption for the biomaterials to the plate for analysis. There is no need for covalently bonding, rather the absorption can be done by "electrostatic charge" (See Col. 2, line 21-25).

Second, the analyte from Thiagarajan et al. device can emit signal for detection purpose (See Figure 6, Figure 7 and Figure 8; Table 1). The analyte is oxygen, the biostructure is a specified E.coli strain (ZK211; W3110 rans-2-trpA-) embedded in the biostructure wherein upon the contract with the analyte, the biostructure would produce response and emit signal detectable by Chessell 4001 recorder (See Materials and Methods).

Lastly, with respect to the product by process argument (e.g. printing method), applicant recites that the device is "obtainable" by gravure coating, piezoelectric printing or acoustic printing (emphasis added). The case law has established that the production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art- "[Where] the claimed and prior art products are identical or substantially identical in *structure or composition*, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)(emphasis added). This is particularly true when the

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properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art. See In re Kind, 207 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143, 144-145 (CCPA 1938); In re Bergy, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). Therefore, the biostructure per se is unpatentable over the same product taught by Thiagarajan and Foster et al.

With respect to the 3-Dimension embodiment, examiner would like to point out that every material is a 3-dimensional structure. For the large number of microwell or microplate, it is of note that there is no recitation in the claim language. Second, merely for using the biostructure including microwell or microplate is not novel because Foster et al. teach such features (See Background of the Invention, Col. 1, line 1-38; Example 1).

Cantwell reference (EP 0288203)

Applicant argues that Cantwell et al. emphasize the preparation of porous compositions that allow a substrate to come into contact with a cell and thereby teaches away from composite devices that include nonporous components.

Applicant's argument has been considered but is not persuasive.

As discussed above that using nonporous latex material for microplate or test tube is well known and widely practiced in the art (See Foster et al. reference). Examiner did NOT rely on Cantwell et al. reference for this recited feature (emphasis added). Rather, Cantwell et al. reference provides the suggestion and motivation to immobilize target molecules on the latex

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polymers, such as cross-linking method as recited in claim 14 and 105. It is of course that the substrate has to be porous to allow oxygen or nutrients to reach the biological materials, e.g. E Coli. The nonporous material is taught and suggested by Foster et al., not by Cantwell et al.

Conclusion

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641



September 12, 2005



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/19/05